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In re Application of
Stephen Mayo et al
Serial No.: 10/074,679 : PETITION DECISION
Filed: February 11, 2002
Attorney Docket No.: A-71138-1

This is in response to the petition under 37 CFR 1.181, filed September 22, 2006, requesting entry of an amendment and withdrawal of the Non-Compliant Amendment Notice.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 and contained claims 1-17 directed to a method for generating a protozyme. The examiner mailed a first Office action to applicants requiring an election of species with respect to claims 3-4 (timing of the insertion step) and claims 7-9 (type of active site). Applicants replied on March 15, 2004, amending claims 1 and 12, canceling claim 15 and electing the timing of insertion of claim 2 and active site of claim 7. Claim 1 was changed to a method for screening for protozymes. The election was made without traverse in view of M.P.E.P. 803.02.

The examiner mailed a new Office action to applicants on May 28, 2004, acknowledging the elections and rejecting claims 13-14 under 35 U.S.C. 112, second paragraph, as indefinite. Claims 1-2, 5-7, 10-14 and 16-17 were rejected under 35 U.S.C. 112, first paragraph, as lacking enablement. Claims 1-2, 5-7, 13-14 and 16 were rejected under 35 U.S.C. 102(b) as anticipated by WO 9853849. Claims 1-2, 5-7, 13-14 and 16 were also rejected under 35 U.S.C. 102(b) as anticipated by admitted prior art in the specification (Hellinga et al, Robertson et al and Klemba et al). Claims 10-12 and 16-17 were rejected under 35 U.S.C. 103(a) as unpatentable over WO 9853849 or Hellinga et al, Robertson et al, or Klemba et al in view of Brenner et al or admitted prior art. Claims 1-2, 5-7, 13-14 and 16 were further rejected under 35 U.S.C. 103(a) as obvious over US 6188965, US 6269312 and others in view of Anderson (US 6180343).

Applicants replied on November 29, 2004, canceling claims 1-17 and adding claims 18-26 directed to a method of identifying enzymes with novel catalytic activity and responding to the rejections of record.

The examiner mailed a Notice of Non-responsive amendment – that the newly added claims do not read on the previously elected invention – to applicants on February 23, 2005, setting a one month period for reply.

Applicants replied on May 23, 2005, amending claims 18, 20 and 22 and argued that the claims were directed a species of the originally claimed invention.

The examiner mailed to applicants a new Notice of Non-responsive amendment on August 1, 2005, setting a one month period for reply, maintaining that the amendment now presented was still non-responsive and explaining why applicants' arguments were not accepted.

Applicants replied on February 1, 2006, canceling claims 1-27 and adding new claims 28-36, directed to a method for screening protozymes and again responding to all of the rejections of record with respect to the newly added claims.

The examiner mailed another Notice of Non-responsive amendment to applicants on June 16, 2006, setting a one month period for reply, stating that the newly added claims are directed to a patentably distinct method from that originally presented.

Applicants filed this petition on September 22, 2006, requesting entry of the amendment and consideration thereof and also filed a further reply to the Notice of Non-responsive amendment maintaining claims 28-36 and adding claims 37-45.

DISCUSSION

Original claim 1, the only independent claim reads as follows:

- 1. A method for generating a protozyme, said method comprising:**
 - a) identifying a suitable protein scaffold lacking a desirable enzyme-like activity;**
 - b) inputting a protein backbone structure of said protein scaffold into a computer, wherein said backbone structure has variable residue positions;**
 - c) inserting an active site domain into said scaffold;**
 - d) applying at least one protein design cycle; and**
 - e) generating a set of candidate variant proteins with putative enzymatic-like activity.**

And was amended following the election of species requirement, as follows:

1. (Currently amended) A method of screening for generating ~~a~~ protozymes, said method comprising:

- a) identifying a suitable protein scaffold lacking a desirable enzyme-like activity;
- b) inputting a protein backbone structure of said protein scaffold into a computer, wherein said backbone structure has variable residue positions;
- c) inserting an active site domain into said scaffold;
- d) applying at least one protein design cycle; and
- e) generating a set of candidate variant proteins with putative enzyme-like activity[.];
- f) synthesizing a plurality of said candidate variant proteins with putative enzyme-like activity; and,
- g) testing said candidate variant proteins with putative enzyme-like activity and selecting at least one of said candidate variant proteins with enzyme-like activity.

Claim 5 adds a further limitation that the insertion step c) "comprises the use of at least one high energy state rotamer". Claims 1 and 5 were both rejected in the Office action of May 28, 2004, for various reasons.

In response applicants canceled claims 1 and 5 and added independent claim 18, as follows:

18. (New) A method of identifying enzymes with novel catalytic activity, comprising:

- a) inputting the three dimensional coordinates of a target protein structure with variable residue positions into a computer;
- b) inserting one or more high energy rotamers into said target protein;
- c) applying at least one protein design cycle to the target protein structure;
- d) generating a set of candidate enzymes with putative catalytic activity;
- e) synthesizing a plurality of said candidate enzymes;
- f) testing said candidate enzymes for said catalytic activity; and
- g) selecting at least one candidate enzyme with catalytic activity.

Claim 18 included the limitation of high energy state rotamers as step b), but was considered non-responsive as it was not directed to method of generating or screening for protozymes.

Applicants in reply to the Notice of Non-responsive amendment of February 1, 2006, canceled claim 18 and added claim 28, as follows:

28. (New) A method of screening for protozymes, said method comprising:

-  a) identifying a suitable protein scaffold lacking a desirable enzyme-like activity;
- b) inputting a protein backbone structure of said protein scaffold into a computer, wherein said backbone structure has variable residue positions;
- c) inserting an active site domain into said scaffold comprising the use of one or more high energy state rotamers;
- d) applying at least one protein design automation algorithm using high energy rotamers comprising:
 - i) establishing a group of variable position rotamers for each of said variable positions;
 - ii) analyzing the interaction of each said high energy rotamers with said variable position rotamers; and
 - iii) analyzing the interaction of each said high energy rotamers with the remainder of said protein backbone;
- e) generating a set of candidate variant proteins with putative enzyme-like activity;
- f) synthesizing a plurality of said candidate variant proteins with putative enzyme-like activity; and,
- g) testing said candidate variant proteins with putative enzyme-like activity and selecting at least one of said candidate variant proteins with enzyme-like activity.

As can be seen, claim 28 is directed again to screening protozymes, as in original claim 1, as amended prior to first action, and includes as step c) the insertion of a high energy rotamer. The examiner's statement in the last Notice of Non-responsive amendment, dated May 16, 2006, specifically: "the defining method step in the new claims is directed to inserting rotamers related to a substrate, rather than a protozyme, and is thus different from the method as originally claimed" is not supported by the record.

Original claim 1 requires an insertion step and is further modified by claim 5 which specifies that the insertion is of high energy state rotamers. Claims 1 and 5 were fully considered and rejected in the first Office action on the merits of the application dated May 28, 2004. The examiner's explanation as to why the limitation makes the amendment non-responsive appears to relate more to support in the disclosure in the specification and the requirements of 35 U.S.C. 112, first paragraph, rather than to whether the amendment is responsive or not.

Applicants' petition requests that claims 28-36 be examined with newly added claims 37-45 inasmuch as claims 28-36 are responsive to the Office action mailed May 28, 2004, and are not directed to an embodiment not encompassed within the claims as examined.

DECISION

The petition to examine claims 28-36, as presented in the amendment of February 1, 2006, with the claims now added by the amendment of September 22, 2006, is **GRANTED**.

The application will be forwarded to the examiner for consideration of the amendment filed September 22, 2006, and further action not inconsistent with this decision.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number 571-273-8300.



George C. Elliott
Director, Technology Center 1600

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